

REMARKS

I. Amendments

By this amendment, claims 1, 3 and 6 have been amended and claim 2 has been cancelled.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

No amendment of inventorship is necessitated by this amendment.

II. Acceptability of the Drawings – Second Request for Consideration

Applicants note that seven pages of drawings (Figures 1-7) accompanied the specification as originally filed. Applicants respectfully request for the second time that the Examiner indicate whether or not the drawings are acceptable. If the drawings are unacceptable, Applicants respectfully request that they be provided a Notice of Draftsperson's Patent Drawing Review.

III. Discussion of the Further Restriction Requirement.

The Examiner indicated that claim 5 as previously amended should be restricted from the other pending claims in the Office Action. Accordingly, claim 5 has been indicated to be withdrawn.

IV. Discussion of the Rejection under 35 U.S.C. Sec. 101

Claims 1-3 and 6 have been rejected under 35 U.S.C. 101 as allegedly lacking utility. Applicants respectfully traverse the rejection.

The present inventors have found cDNA having a novel base sequence at high levels in the lungs, trachea and stomach as illustrated in Example 2. Furthermore, as proven by Example 7, a protein encoded by said cDNA is a humoral factor secreted extracellularly.

When the protein of the present invention or the DNA of the present invention is abnormal or defective, or its expression is abnormally reduced or promoted, there occur various

diseases such as immune diseases, pulmonary insufficiency, pancreatic insufficiency, infectious diseases or gastrointestinal disorders.

Accordingly, Applicants' protein as set forth in claim 1 as amended can be used as a pharmaceutical preparation for treating diseases such as trachea and bronchus-related diseases such as bronchitis, influenza and bronchial asthma; for treating lung-related diseases such as lung cancer, tuberculosis and pneumonia; and diseases of the stomach such as gastritis.

The Examiner's remarks in the last paragraph of page 3 of the Office Action to the first paragraph of page 4 seem to indicate that the Examiner does not find Applicants' asserted utility to be credible. Applicants disagree, and request that the Examiner provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. They do not believe that their assertions violate any scientific principles nor laws of nature nor are wholly inconsistent with contemporary knowledge in the art.

In addition to the utilities which the Applicants have explained to the Examiner in a previous communication and re-emphasized in the foregoing paragraphs, the Applicants also wish to draw the Examiner's attention to the portions of the specification describing an aspect of their invention as a genetic diagnostic agent. Page 40, paragraph 215 – page 41, paragraph 218 of the specification describes this use of the invention. Applicants believe that such a use satisfies the utility requirement.

Yet another utility of the present invention is that of utility as a screening agent, which can be explained as follows. Compounds or salts thereof which inhibit the function of the protein as set forth in claim 1 as amended can be used in pharmaceutical preparations for treating diseases attributable to excessive production of said proteins. Accordingly, the proteins of the present invention are useful as reagents for screening for a compound or salt thereof which promotes or inhibits the function of the protein of the present invention. Applicants believe that such a use also satisfies the utility requirement.

Claim 2 has been cancelled. Claims 3 and 6 depend upon claim 1. Applicants assert that the more specific dependent claims also have utility for the reason provided above.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 101 rejection of claims 1, 3 and 6.

V. Discussion of the Rejection under 35 U.S.C. Sec. 112, First Paragraph

Claims 1-3 and 6 have been rejected under 35 U.S.C. Sec. 112, first paragraph, as allegedly lacking enablement. Applicants respectfully traverse the rejection.

Applicants hereby incorporate their arguments made in Sec. IV above to overcome this rejection.

Applicants disagree with the Examiner's conclusion that their invention is not supported by specific utility. They believe that their invention has specific utility. Since it has utility, one skilled in the art would understand the invention, given the teachings of the specification.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection.

VI. Discussion of the Rejection under 35 U.S.C. Sec. 112, Second Paragraph

Claims 1-3 and 6 have been rejected under 35 U.S.C. Sec. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse the rejection. Each aspect of the rejection will be discussed in the following paragraphs.

In the first aspect of the rejection, the Examiner has objected to the phrase "represented by" in claim 1. By this amendment, Applicants have adopted the Examiner's suggestion to replace "represented by" with "of".

In the second aspect of the rejection, the Examiner has indicated that "partial peptide" in claim 2 is indefinite. To advance prosecution of the application, Applicants have cancelled claim 2 and the objected to subject matter in claims 3 and 6.

Claims 3 and 6 depend upon claim 1. Applicants assert that the more specific dependent claims are also sufficiently clear for the reason provided above.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, second paragraph rejection.

VII. Discussion of the Rejection under 35 U.S.C. Sec. 102(a) over Rosen *et al.*

Claims 2, 3 and 6 have been rejected under 35 U.S.C. Sec. 102(a) as allegedly being anticipated by Rosen *et al.* (WO 98/45712). Applicants respectfully traverse the rejection.

By this amendment, claim 2 has been cancelled and the recitation of "partial peptides" has been accordingly deleted from claims 3 and 6. Applicants assert that claims 3 and 6 as amended are not anticipated by the cited reference.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 102(a) rejection.

VIII. Conclusion

Reconsideration of the claims and allowance is requested.

Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

Dated: December 29, 2004

(847) 383-3391
(847) 383-3372

Elaine M. Ramesh
Elaine M. Ramesh, Ph.D., Reg. No. 43,032
Mark Chao, Ph.D., Reg. No. 37,293
Attorney for Applicants
Customer No. 23115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
475 Half Day Road
Lincolnshire, IL 60069 USA

Certificate of Mailing under 37 CFR 1.10

The undersigned hereby certifies that this document, along with any attachments, is being deposited in an envelope addressed to The Commissioner of Patents and Trademarks, with sufficient postage with the United States Postal Service EXPRESS MAIL Post Office to Addressee Service on this date December 29, 2004

Express Mail Label No. EV 524906756 US

Dawn Hackbert

Printed Name: Dawn Hackbert